REMARKS

The claims have been amended to address the language objections, and also to better distinguish the claimed invention from the prior art. Support for the amendment of independent claim 1 may be found in the specification at p 10, line 24, through p 11, line 6. (See also Fig. 7). No new matter has been added.

Turning to the art rejections, and considering first the rejection of claim 1 under 35 U.S.C. § 103(a) as being unpatentable over Charbel et al. (U.S. Patent No. 7,191,110) in view of Okada et al. (U.S. Patent No. 6,673,020) (both previously cited), in view of Kamm et al. (U.S. Patent No. 6,117,087) (newly cited) independent claim 1, as amended, requires in part "wherein the error is computed as a difference between a component in the ultrasonic beam direction of the blood flow velocity vector obtained by said simulation unit and a corresponding component in the ultrasonic beam direction of the blood flow velocity vector obtained by said analysis processing unit." It is submitted that neither of the cited prior art references teach or for that matter suggest this feature.

Charbel et al. is cited by the Examiner as teaching "a feedback unit which computes an error between the blood flow velocity obtained by said analysis processing unit and the blood flow velocity obtained by said simulation unit." As noted in Applicant's earlier Amendments, incorporated herein by reference, the Examiner mischaracterizes Charbel et al. Charbel et al. provides a method and apparatus for "modeling circulation in a living subject," by "developing a model for living subjects in general and correcting the model to substantially conform to the overall cerebral physiology of the living subject." (Abstract, emphasis added). The text of Charbel cited by the Examiner goes on to explain:

The present invention is a refined model that is capable of being adapted to specific patients. . . . <u>Deviations of the arterial structure</u> of the blood supply of

HAYES SOLOWAY P.C. 3450 E. SUNRISE DRIVE, SUITE 140 TUCSON, AZ 85718 TEL. 520.882.7623 FAX. 520.882.7643

the patient's brain from the general model are <u>identified from the angiograms</u>. An x-ray angiogram of the patient's brain is used to determine the <u>diameter of</u> the blood vessels.

(Col. 17 line 58 – 67) This description cannot be said to teach "a feedback unit which computes an error between the blood flow velocity vector obtained by said analysis processing unit and the blood flow velocity obtained by said simulation unit" as required by claim 1. Charbel et al. does not teach computing an error between the two blood flow velocities at all, but rather determines the error between the model's blood vessel <u>physiology</u> and that of the patient as determined by visualization procedures. The subsequent calculations of flow velocities and pressure are computed without any data feedback refinement.

It is not seen that the secondary reference Okada et al. supplies the missing teachings to Charbel et al. to achieve or render obvious claim 1. Okada et al. has been cited as teaching an ultrasonic measurement unit that emits an ultrasonic signal towards a blood vessel in a human body to receive the reflected ultrasonic signal. Even assuming arguendo Okada et al. is as the Examiner characterizes this reference, it does not supply the more basic and essential features missing from the primary reference Charbel et al. as discussed above. Accordingly, it is submitted that no combination of Charbel et al. and Okada et al. could be said to achieve or render obvious claim 1.

The newly cited U.S. patent to Kamm et al. does not provide the missing teachings to the Charbel et al./Okada et al. combination. Kamm et al. provides:

In step 81, a set of parameter values is first chosen at random, and in step 82 the surrogate is used to calculate the predicted feature values. In step 83, these computed features are compared to the values extracted from the experimental measurement 72 and a measure of the error or difference between the two sets is obtained. In step 84, a test is performed, and if this error is small enough to meet some predetermined criterion, the procedure deems the fit to be good and in step 85 provides as output the corresponding set of parameter values. If in step 84 the error criterion is not met, the trial values are modified in stop 86 and now feature

HAYES SOLOWAY P.C. 3450 E. SUNRISE DRIVE, SUITE 140 TUCSON, AZ 85718 TEL. 520.882.7623 FAX. 520.882.7643

values are computed again in stop 82. This process continues until such time as the error criterion is satisfied and the cycle terminates with a solution in stop 85. (Col. 17, lines 48-46)

The computed error in this scheme is not fed back "to a number of representative points which are distributed over a blood flow domain in said computational lattices of said simulation unit." In fact, Kamm does not use the computed error at all except to compare it to some predetermined error criterion. Then, the trial values are modified, possibly at random, and a new computation is produced and compared to experimental data. Furthermore, Kamm et al. describe six parameters that may be solved using the above system. Flow velocity is not among the enumerated parameters. Accordingly, Kamm et al. cannot be said to provide the missing teachings to the Charbel et al./Okada et al. combination. Specifically, no combination of Charbel et al., Okada et al. and Kamm et al. teaches or suggests "a feedback unit which computes an error between the blood flow velocity vector obtained by said analysis processing unit and the blood flow velocity obtained by said simulation unit and feeds back the error to a number of representative points which are distributed over a blood flow domain in said computational lattices of said simulation unit."

Similar commens apply to Cawlfield (also newly cited) which the Examiner applies as an alternative to Kamm et al. The Examiner contends that Cawlfield discloses an automatic control system for unit operation and further teaches that real values can be compared to simulated values and the difference can be used to update the simulation. Assuming, arguendo, that Cawlfield is as the Examiner describes, Cawlfield does nothing to cure the deficiencies of the Charbel et al./Kamm et al. combination in teaching "a feedback unit which computes an error between the blood flow velocity vector obtained by said analysis processing unit and the blood flow velocity obtained by said simulation unit and feeds back the error to a number of

HAYES SOLOWAY P.C. 3450 E. SUNRISE DRIVE, SUITE 140 TUCSON, AZ 85718 TEL. 520.882.7623 FAX. 520.882.7643

representative points which are distributed over a blood flow domain in said computational lattices of said simulation unit." Thus, the combination of Charbel et al., Kamm et al. and Cawlfield also cannot be said to achieve or render obvious claim 1.

Hayase et al. 1997 and Hayase et al. 2002 also fail to supply the missing teachings to the Charbel et al./Okada et al. combination to achieve or render obvious claim 1. Both Hayase references deal with using a pressure correction feedback loop in determining flow. (see Hayase 1997 p. 818 "As to the input variables, the pressure boundary condition is modified through the simple proportional feedback law. The pressure difference proportional to the estimation error is added to the constant pressure difference . . . to reduce the estimation error." And Hayase 2002 P. 5 "The velocity component is accelerated or decelerated by the feedback of eq. (5) at the upstream boundary of the pressure control volumes. As a result the pressure error in the pressure equation decreases in these control volumes.") These feedbacks describe the SIMPLER method of Fig. 1 of the present application. The SIMPLER method has significant problems that are addressed by the present invention. The claims of the present invention require the computation and feedback of a velocity vector, as opposed to the pressure in the blood vessel. The difference is not academic. As the specification states:

[I]n order to reproduce the actual blood flow by using the above described [SIMPLER] numerical simulation of the flow field, it is necessary to give a complete state (initial condition) of the blood flow at a certain time and a state in a boundary surface (boundary condition) through all times. . . . [A]s the assumption that the blood flow is the uniform flow in parallel with a blood vessel wall is not always valid in the actual blood flow, an error due to the inappropriate boundary condition cannot be avoided.

(Specification page 4-5 and 10-11) In other words, "[i]n the conventional numerical simulation, the results of the velocity components u and v differ from the results of the standard

HAYES SOLOWAY P.C. 3450 E. SUNRISE DRIVE, SUITE 140 TUCSON, AZ 85718 TEL. 520.882.7623 FAX. 520.882.7643

solution respectively. The difference is caused by the insufficient lattice spacing of the computational lattice." (Page 14). In the present invention:

when the numerical simulation and the measurement are simultaneously performed, the velocity vector obtained by the numerical simulation is set to u_c and expressed in a two-dimensional way. A difference between a component in the ultrasonic beam direction of the velocity vector u_c obtained by the Navier-Stokes equation which is of the momentum conservation equation and a corresponding velocity component of the velocity vector u_m in the ultrasonic beam direction obtained by a measurement is fed back to the body force term in the Navier-Stokes equation (page 11-12). Since the error in the y-direction was fed back to the measurement integrated simulation the result substantially equal to the standard solution is obtained for the y-direction velocity v_m , and the result close to the standard solution compared with the conventional simulation is obtained for the x-direction velocity v_m . (page 14).

Accordingly, none of the materials cited by the examiner, either alone in combination, teach or suggest a simulation unit which sets computational lattices on the basis of the blood vessel shape obtained by said analysis processing unit to simulate the blood flow velocity vector and a pressure distribution; and a feedback unit which computes an error between the blood flow velocity vector obtained by said analysis processing unit and the blood flow velocity vector obtained by said simulation unit in two dimensions and feeds back the error to a number of representative points which are distributed over a blood flow domain in said computational lattices of said simulation unit, as required by the amended claims.

Turning to the rejection of claims 3 as being unpatentable over Charbel et al. in view of Okada et al., Kamm et al. or Cawlfield et al. or Hayase et al. ("State Estimator of Flow as an integrated Computational Method with the Feedback of Online Experimental Measurement", Transactions of the ASME, J. Fluids Eng., Vol. 119 (1997)) and further in view of Hayase et al. ("Numerical Realization of Flow Field by Integrating Computation and Measurement", Proceedings of 5th World Congress on Computational Mechanics (2002)), claim 3 depends upon claim 1. The deficiencies of the cited art vis-à-vis claim 1 are discussed above. Thus, no

HAYES SOLOWAY P.C. 3450 E. SUNRISE DRIVE, SUITE 140 TUCSON, AZ 85718 TEL. 520.882.7623 FAX. 520.882.7643

combination of Charbel et al. and Okada et al. with Kamm et al. or Cawlfield et al. or Hayase et al. (1997) in further view of Hayase et al. (2002) can render obvious claim 1 or claim 3, which depends thereon.

Quite apart from the foregoing, the Examiner appears to have reached erroneous conclusions in applying the art. The Examiner takes the position:

"It would be obvious design choice to have performed the calculations another way."

"Obvious design choice" is understood to mean belonging to the category of a predetermined design aspect.

The design object (A) and the design variables (B) are typically important elements of a design aspect.

The present claimed invention involves a method for <u>obtaining a correct result using</u>

measurement results in a case where a correct response cannot be obtained merely by

simulation alone. Art described in the cited documents that fulfill a similar objective were

variously discussed in the Examiner's Action, and are represented below in terms of their design aspects.

HAYES SOLOWAY P.C. 3450 E. SUNRISE DRIVE, SUITE 140 TUCSON, AZ 85718 TEL. 520.882.7623 FAX. 520.882.7643

		(A) Design object	
		(1) Incorrect model (lattice resolution, shape, etc)	(2) Incorrect inflow or outflow boundary condition
(B) Design variable	(i)Model parameter (not including inflow/outflow boundary condition parameter)	Common knowledge (widely practiced) Charbel et al., Kamm et al., Cawlfield, etc.	n/a
	(ii) Inflow/outflow boundary condition parameter	Hayase et al., '97	Common knowledge (widely practiced) Charbel et al., Kamm et al., Cawlfield, etc.
	(iii) Parameters other than the model parameter, and inflow/outflow boundary condition parameter (body force added into computation region, etc.)	Hayase et al., '02	Present invention

The use of the categories of (1) incorrect model and (2) incorrect inflow/outflow boundary condition for the design object (A), and the fact that there are completely different aspects, are well-known facts of differential equation theory.

One could also consider it suitable to classify the design variables (B) into parameters (i) and (ii), which correspond to (1) and 2); and into parameter (iii), which is neither of the above.

The classifications of (A) and (B) are typical classifications used in differential equation theoretical systems, and in the opinion of the inventor it makes sense to regard aspects in different blocks in the same category.

Items (i) and (ii) (respectively corresponding to (1) and (2), in which the parameters of the design object (A) are used as design variables, are widely used in the design variables (B),

HAYES SOLOWAY P.C. 3450 E. SUNRISE DRIVE, SUITE 140 TUCSON, AZ 85718 TEL. 520.882.7623 FAX. 520.882,7643

long

and the example of Charbel et al., Kamm et al., Cawlfield, etc. cited by the Examiner belong to those categories. Hayase et al., '97 and Hayase et al. '02 are aspects in which object (1) (incorrect model) was designed using the parameters of (ii) and (iii), respectively. In the present claimed invention object (2) (incorrect inflow/outflow boundary condition) was designed using the parameter of (iii).

Having dealt with all the objections raised by the Examiner, the Application is believed to be in order for allowance. Early and favorable action are respectfully requested.

In the event there are any fee deficiencies or additional fees are payable, please charge them (or credit any overpayment) to our Deposit Account Number 08-1391.

Respectfully submitted,

Norman P. Soloway Attorney for Applicants Reg. No. 24,315

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 10, 2008, at Tucson, Arizona.

By

NPS:CEP:ps

HAYES SOLOWAY P.C. 3450 E. SUNRISE DRIVE, SUITE 140 TUCSON, AZ 85718 TEL. 520.882.7623 FAX. 520.882.7643